15 September 2005 DON HRPP News Blast

The Department of Navy's Human Research Protection Program (DON HRPP) continues to build one unified program supporting all research aimed at improving the lives of our war fighters and their families. We are reevaluating, merging, and streamlining policies, procedures, and practices for human research protections

In the spirit of keeping you updated, some of the progress and next steps:

1. SECNAVINST 3900 series, Protection of Human Subjects.

Many thanks to all those individuals and commands who provided comments and feedback on the draft SECNAVINST 3900.39D. The DON HRPP working group considered the items and determined how to best use them. The SECNAVINST is now working through the "chop chain" for SECNAV's signature. Once it is signed, we will distribute.

2. Surgeon General (SG) Delegates Authority to Chief of Naval Research (CNR).

In a 4 August 2005 letter the SG delegated research approval and oversight for certain DON commands and CNR-supported extramural research to the CNR. The SG retains authority for approving DOD Navy assurances and accepting other federal assurances. See attached SG letter.

3. Assurances. Based on your feedback, we revised the Assurance application and its companion directions. Those commands with assurances expiring soon (through October 2005) may use the earlier version. However, we ask you to verify that you are using the most current version prior to completing the application. Until the DON HRPP website is up and running, we will continue to send updated documents to you via news blasts. You may also wish to contact us to verify the current version. See attached assurance application (v19 29 Aug 2005) and directions (v15 5 Sep 2005) for completing it.

4. Joint Research Review Agreements. We finalized a "model" agreement that commands may use for (1) collaborating and conducting joint research with both commands' IRBs conducting reviews; (2) collaborating and conducting joint research using one reviewing IRB; and (3) one command conducting the research while another command's IRB serves as the reviewing IRB. See attached agreement (v6 28 Aug 2005) and directions (v3 5 Sep 2005) for completing it.

5. Assurance and Research Approval Authority.

The Research and Development laboratories (R&D) and the Clinical Investigation Program (CIP) evolved separately and developed their own polices and procedures for reviewing assurances and granting research approval authority. With the merge of all DON human subject research under one program, we have developed guidance for the transition to unified policies and procedures. The guidance addresses currently-approved assurances, new assurances, and renewal of currently-approved assurances. See attached guidance dated 1 Aug 2005.

6. DON HRPP Directory.

Thank you to everyone who has been diligent in keeping us informed of changes in their institution's contact information. The directory is a continual "work-in-progress" and the main tool we have, right now, to ensure that you get the information you need. See attached directory dated 15 Sep 2005.

7. Next Steps:

      a. Education Policy and Program.

            The education policy and a web-based human subject research educational program are close to being finalized. The Collaborative Institutional Training Initiative (CITI)

program has an additional DoD-DON-specific module to address our additional unique requirements. DON HRPP will support this program for all DON commands and personnel. More details soon.

b. DON HRPP website.

We are developing a website that will eventually host all the relevant guidance, DON HRPP policies and procedure, periodic news blasts, and educational information. Any one with ideas, suggestions, or interested in helping with the content or design of the website, please contact us.

c. Human Research Knowledge System (HKRS).

After a bit of an unforeseeable hiatus and some road bumps, we are now revitalizing HKRS and addressing concerns from our users. We are hoping that the new features, less-intense data entry, and better file cabinets will be more useful. By way of background, HRKS is a centralized web-based information system that tracks all research protocols through the review process and allows the storage of all research protocol files, IRB meeting minutes etc. electronically. The R&D and Systems Commands have been using HKRS for about a year. We hope to have the CIP commands incorporated this fall. More to follow.